

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Study of effect peer education on adherence to therapeutic regimen in patients with type 2 diabetes

Protocol summary

Study aim

The effect of peer education on adherence to therapeutic regimen in patients with diabetes type 2

Design

At First, six of the type 2 diabetic patients who have the ability to study and Inclusion criteria are selected as peers. They will be given to them before going to diabetes education, and then the researcher will train 2 days a week for 2 hours according to their needs for diabetes. After completing the training, they will be taken from them and 3 will be selected from those who have the highest score . The peers in the presence of the researcher will conduct the exercises necessary for the correct implementation of the training. Then, samples of diabetes patients who come to the diabetes clinic and the criteria for entering the study will be selected. Subsequently, they will be given a " Compliance questionnaire on diabetes treatment" and patients who score poorly to Medium will be included in the study. Then, for each patient, a code is assigned and divided into two groups of 50 patients according to the random numbers table. The control group receives regular diabetic clinic training and the test group receive peer education and diabetes clinics.

Settings and conduct

Conducting classes in Amol Endocrinology Clinic in 2 sessions and 2 weeks per week for 2 hours in 2 groups of 25 patients, 50 of them in the intervention group and 50 in the control group

Participants/Inclusion and exclusion criteria

Inclusion criteria: Have at least 6 months diagnosed with type 2 diabetes by doctor: Exclusion criteria: Participating in training program in the last 6 months

Intervention groups

intervention group, patients with type 2 diabetes are being trained by their peers and diabetes clinic for compliance with the diet control group, type 2 diabetic patients receive routine diabetes clinics for adherence to the treatment regimen.

Main outcome variables

Adherence to the Therapeutic Regimen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170703034877N2**

Registration date: **2018-04-24, 1397/02/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-24, 1397/02/04**

Update count: **0**

Registration date

2018-04-24, 1397/02/04

Registrant information

Name

Seyede Marzie Norani

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
Faculty of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 5367

Email address

norani40@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid-Beheshti University of Medical Sciences

Expected recruitment start date

2018-02-08, 1396/11/19

Expected recruitment end date

2018-06-14, 1397/03/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of effect peer education on adherence to therapeutic regimen in patients with type 2 diabetes

Public title

Study of effect peer education on adherence to therapeutic regimen in patients with type 2 diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with type 2 diabetes who have been diagnosed by their physician for at least 6 months The possibility for the patient and the active member of his family to attend classes

Exclusion criteria:

Participating in training program in the last 6 months
Having Physical or psychological problems in person
Inability to read and write
Need to have any surgery
Inability to speak Persian

Age

From **21 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, according to the inclusion criteria , patients were selected; and then each one is given a code and then ; using the random numbers table , the patients will be placed in two groups of intervention and control.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1**

Ethics committee

Name of ethics committee

Ethics Committee of Shahid- Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, adjacent to Ayatollah Taleghani Hospital, Shahid Araji Street., Yemeni Ave., Shahid Chamran Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2016-05-07, 1395/02/18

Ethics committee reference number

IR.SBMU.PHNM. 1394.272

Health conditions studied**1****Description of health condition studied**

Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

Adherence to therapeutic regimen

Timepoint

Before, immediately and 3 month after the intervention

Method of measurement

questionnaire

Secondary outcomes**1****Description**

Hemoglobin A1c

Timepoint

Before and 3 month after the intervention

Method of measurement

Blood-test

2**Description**

Fast blood sugar

Timepoint

Before and 3 months after the intervention

Method of measurement

Blood-test

3

Description

Weight

Timepoint

Before and three months after the intervention

Method of measurement

Scales

Intervention groups

1

Description

Intervention group: Patients with type 2 diabetes receiving diabetes clinics and their counterparts in two 2-hour sessions on adherence to the diet.

Category

Lifestyle

2

Description

Control group: Patients with type 2 diabetes who only receive diabetes clinic training

Category

Lifestyle

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Reza Hospital, Amol City, Mazandaran Province

Full name of responsible person

nadereh naderiravesh

Street address

Imam Reza Hospital, Imam Reza Street

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4614937597

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+98 11 4327 4012

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N.naderiravesh@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. afshin zarghi

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velenjak street . Sheid Beheshti Medical Science University

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Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nadereh Naderiravesh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Faculty of Nursing and Midwifery, In Front of Shahid Rajaei Heart Hospital, Intersection of Niayesh, Tehran

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Person responsible for scientific inquiries

Contact

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work**Street address**

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Person responsible for updating data

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Marzie norani

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Master of medical surgical nursing

Latest degree

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available